**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| SMITH KLINE & FRENCH LABORATORIES LIMITED and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, | ) | |
| Plaintiffs, | ) | Civil Action No. 05-197-GMS |
| v. | ) | |
| TEVA PHARMACEUTICALS USA, INC., | ) | **FILED UNDER SEAL** **Redacted Version of DI 77** |
| Defendant. | ) | |

**PLAINTIFF GLAXOSMITHKLINE'S BRIEF IN OPPOSITION TO DEFENDANT'S MOTION FOR LEAVE TO AMEND ITS ANSWER, DEFENSES, AND COUNTERCLAIMS**

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Dated: July 13, 2006

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## SUMMARY OF ARGUMENT

Almost a month after the deadline for seeking factual discovery and in the midst of expert discovery, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") moves to amend its answer and counterclaims to add claims of inequitable conduct to this patent infringement action. Teva's proposed amendment would greatly expand the scope of this case at a time when fact discovery has ended, expert discovery is already underway, and the deadline for seeking summary judgment has passed. For at least the following three reasons, the motion to amend should be denied or, if the motion is allowed, a new scheduling order should be entered adjusting the deadlines for discovery and summary judgment and continuing the trial date.

*First*, Teva unduly delayed in raising these new claims. Teva's June 28, 2006 motion to amend comes nearly eight months after the deadline for such motions, and nearly one month after the deadline for seeking fact discovery. Teva seeks to give the impression that its delay is excusable because its motion is based upon "recently discovered evidence." In truth, Teva's own foot-dragging is responsible for the belated assertion of its inequitable conduct allegations. Teva chose to wait until the very end of the fact discovery period to seek relevant deposition testimony – including waiting until the *final week* of the fact discovery period to request depositions on patent prosecution issues. With respect to other evidence cited by Teva in support of its eleventh-hour motion, Teva was aware of the information many months ago yet chose to sit on its hands rather than pursue additional discovery or raise these issues in a timely manner.

*Second*, Teva's proposed amendment would unduly prejudice Plaintiffs ("GSK") by unfairly limiting GSK's ability to conduct necessary fact and expert discovery. Because Teva waited until after the deadline for pursuing fact discovery to raise inequitable conduct claims, GSK was deprived of the opportunity to develop the factual record to rebut Teva's unsupported

allegations. For example, William Edgerton, who was involved in prosecuting the '808 patent and thus might have provided testimony relevant to Teva's inequitable conduct claims, died in April 2006. GSK informed Teva of Mr. Edgerton's involvement in the '808 patent prosecution on October 3, 2005, yet Teva did not request his deposition until May 24, 2006, one week before the May 31, 2006 fact discovery deadline. Had Teva promptly asserted its inequitable conduct theories, GSK would have had the opportunity to solicit relevant testimony from Mr. Edgerton.

Similarly, a second patent lawyer listed on the face of the patent is the Honorable Alan Lourie, who was the head of GSK's patent department at the time the patents-in-suit were prosecuted. Obviously, GSK would not lightly seek the testimony of a sitting Federal Circuit judge, but Teva's proposed inequitable conduct defenses implicate Judge Lourie's knowledge of the customary practices within GSK's patent department when the patents were prosecuted.

GSK is further prejudiced by the effect of Teva's newly articulated claims and defenses on expert discovery. Expert discovery is well underway, with the first round of expert reports having been produced on July 10, 2006. Yet Teva's new claims will likely require expert testimony in a number of areas not previously at issue in this litigation. For example, Teva's inequitable conduct claims include contentions that generic claims in the patent are not supported by the work of the named inventors. These patent claims are not asserted by GSK against Teva, and therefore there is no need to retain expert assistance to defend the breadth of the claims. Teva's inequitable conduct contentions, however, would reintroduce the generic claims into the case, and thus Teva's motion creates uncertainty regarding the proper scope of expert testimony. In light of the many issues raised for the first time in Teva's motion, GSK will have to prepare additional and potentially unnecessary expert reports in just a few weeks. Furthermore, because GSK did not have the opportunity to conduct fact discovery with respect to certain aspects of

Teva's new allegations, some GSK experts will be forced to prepare their testimony without the benefit of relevant evidence.

*Third,* GSK is significantly prejudiced by Teva's proposed amendment because it arises *after* the deadline for summary judgment motions. Teva's claims of inequitable conduct are legally and factually baseless and ripe for summary judgment on numerous grounds. Perhaps the most conspicuous infirmity in Teva's new claims is Teva's failure to cite any evidence satisfying its high burden of demonstrating an intent to deceive the patent office. Several of Teva's claims are flawed on the face of the amended complaint, such that the Court rightfully could deny the motion to amend as futile. But even if some of Teva's claims could survive a motion to dismiss, Teva's late assertion of these claims is clearly prejudicial because it denies GSK the opportunity to challenge the claims on summary judgment.

## STATEMENT OF FACTS

### I. Nature and Stage of the Case

GSK initiated this lawsuit on April 6, 2005, alleging infringement by Teva of two GSK-owned patents relating to ropinirole hydrochloride: United States Patent No. 4,452,808 ("the '808 patent") which claims certain compounds and pharmaceutical compositions including ropinirole hydrochloride; and United States Patent No. 4,824,860 ("the '860 patent") which claims methods of treatment of Parkinson's Disease with compounds including ropinirole hydrochloride. GSK developed, manufactures and sells Requip®, a commercial formulation of ropinirole hydrochloride that has been approved by the FDA for treatment of Parkinson's Disease and Restless Legs Syndrome. GSK filed suit after receipt of a February 21, 2005 letter from Teva ("the Teva Notice Letter") notifying GSK that Teva had submitted an Abbreviated New Drug Application ("ANDA") containing a Paragraph IV Certification to the FDA for

approval to engage in the commercial manufacture, use, offer for sale, and sale of generic ropinirole hydrochloride tablets prior to the expiration of the '808 and '860 patents.

The Scheduling Order governing this case was entered in August 2005 and later revised by the Court on July 6, 2006. [D.I. 17; D.I. 70] The Scheduling Order, as amended, includes the following deadlines relevant to the present motion:

- August 5, 2005 — Exchange of Initial Disclosures
- November 4, 2005 — Motions to Amend Pleadings
- June 14, 2006 — Letter Briefs Seeking Permission to File Summary Judgment Motions
- June 30, 2006[1] — Completion of Fact Discovery
- July 10, 2006 — Opening Expert Reports
- August 14, 2006 — Answering Expert Reports
- September 1, 2006 — Reply Expert Reports
- September 27, 2006 — Completion of Expert Discovery

A five-day trial is scheduled to begin on December 18, 2006.

## II. Teva's Challenge to the Validity of the Patents-in-Suit

To date, this litigation has been focused on a narrow challenge by Teva to the validity of the patents-in-suit. Specifically, and consistent with its ANDA filing and the Teva Notice Letter, Teva articulated in its October 2005 interrogatory responses a single validity challenge to each patent – an allegation that certain claims of the patents are invalid as obvious under

[1] The fact discovery deadline as set forth in the August 2005 Scheduling Order was May 31, 2006. As discussed below, the parties agreed to extend the fact discovery deadline from May 31, 2006 to June 30, 2006 for the limited purpose of responding to discovery requests and deposition notices served prior to May 31, 2006. In addition, the deadlines for exchanging expert reports were amended in the revised Scheduling Order entered on July 6, 2006.

35 U.S.C. § 103 in light of allegedly relevant prior art.[2] In April 2006, Teva supplemented its interrogatory responses but made no mention of the inequitable conduct claims and defenses it now seeks to raise.[3] The parties have completed discovery on these issues and are prepared to litigate this case within the time allotted by the Scheduling Order.

## III. Agreement to Narrow the Issues in Dispute

In the spring of 2006, the parties agreed to narrow the claims at issue. The parties reached this agreement in principle in May and ultimately submitted a Joint Stipulation and Proposed Order to the Court on June 23, 2006. The Court approved the Order on June 26, 2006. [D.I. 61] In the Order, GSK stipulated that the only claims asserted by GSK to be infringed by Teva are claim 5 of the '808 patent and claim 3 of the '860 patent (the "Asserted Claims"). The Asserted Claims are directed specifically to ropinirole hydrochloride, in contrast to some other claims that cover a broader genus of compounds including ropinirole hydrochloride. Teva, in turn, stipulated that it will not raise any non-infringement defense with respect to the Asserted Claims. Through its proposed amendment, Teva now seeks to couch as inequitable conduct claims challenges to the validity of claims the parties mutually agreed to drop from the case.

## IV. The Course of Fact Discovery

Following an exchange of initial disclosures in August 2005, the parties exchanged interrogatories and document requests in September 2005. Written discovery responses were served in October 2005 and later supplemented in 2006.[4] In response to Teva's broad document

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[2] *See* Teva's Responses to GSK's First Set of Interrogatories, Responses to Interrogatory Nos. 3, 4 (October 3, 2005) (Exhibit A).

[3] *See* Teva's Second Supplemental Responses to GSK's First Set of Interrogatories, Response to Interrogatory No. 4 (April 10, 2006) (Exhibit B).

[4] Each party served and responded to additional written discovery requests in the spring of 2006.

requests, GSK gathered, reviewed, and produced a large volume of documents. GSK's document production, which began in 2005, exceeds 400,000 pages.

**A. GSK's October 2005 Responses to Teva's First Set of Interrogatories**

Teva's motion to amend relies almost entirely on facts and circumstances about the conception and reduction to practice of the inventions claimed in the '808 and '860 patents, which Teva claims to have learned only through depositions in May 2006. In fact, the allegedly newly-discovered facts concerning the inventions described in the '808 patent were known to Teva as early as October 2005. In September 2005 interrogatories, Teva asked GSK to "identify the alleged inventor(s) of the subject matter of the claim, and describe with particularity the facts and circumstances surrounding any alleged conception, reduction to practice, and/or claim to diligence from conception to reduction to practice." In its October 3, 2005 response, GSK clearly described the conception and reduction to practice of the inventions claimed in the '808 patent, stating in part:

> At least as early as 1982, Gallagher conceived of the idea of removing the *para*-OH group from the aromatic ring of 4-aminoalkyl-7-hydroxy-2(3H)-indolone compounds. At least as early as 1982, Gallagher synthesized ropinirole, which lacks the *para*-OH group of the corresponding 4-aminoalkyl-7-hydroxy-2(3H)-indolone compound, thereby reducing to practice the invention claimed in the patent.

Plaintiff GSK's Responses to Defendant's First Set of Interrogatories, Response to Interrogatory No. 3 (Oct. 3, 2005) (Exhibit C). GSK's response makes clear that the reduction to practice of the claimed invention by the named inventor, Gregory Gallagher, (a) involved only the synthesis of ropinirole (not other compounds, as Teva now claims was required), and (b) did not involve any human testing (which Teva now claims was required). Upon receiving these responses, Teva either could have asserted then (as it does now) that these facts demonstrate inequitable

conduct, or it could have pursued further discovery last fall or in early 2006 on these issues. Teva did neither.

Teva has likewise long been on notice of the facts related to its claims about the inventorship of the '860 patent. GSK's October 2005 interrogatory responses state in part:

> In 1985, the development work relating to ropinirole was transferred to the Welwyn Garden City office of SK&F. Dr. Owen was the Director of the Pharmacology Division at the time of the transfer and became a project team member for ropinirole. Based on tests of ropinirole conducted under his direction, Dr. Owen determined that ropinirole caused central nervous system ("CNS") activity and conceived of using ropinirole to treat central nervous system disorders including Parkinson's disease. Further CNS evaluations performed by SK&F in Welwyn and by researchers at the University of Bradford engaged by SK&F further demonstrated ropinirole's potential as an anti-Parkinson's agent.

Plaintiff GSK's Responses to Defendant's First Set of Interrogatories, Response to Interrogatory No. 3 (Exhibit C). Accordingly, Teva knew in October 2005 that the testing commissioned by Dr. Owen concerned ropinirole, and not the other compounds covered by the '860 patent. Likewise, Teva knew at that time that Bradford University scientists (who Teva now suggests should have been named as inventors) confirmed Dr. Owen's belief that ropinirole could be used to treat Parkinson's Disease. If Teva believed (as it now claims) that these facts created an inequitable conduct claim, it either could have asserted that claim or sought more targeted discovery last fall.

**B. Depositions Requested by Teva**

**1. Depositions Requested by Teva on March 15, 2006**

Teva of course knew the identity of the inventors listed on the patents before this lawsuit was filed. Yet Teva waited until March 15 to request the depositions of Mr. Gallagher and Dr. Owen, four months after the deadline for amending the pleadings had expired. In a March 15 letter to GSK, Teva requested the depositions of seven individuals, including the two inventors.

*See* Letter from Karen Robinson to Michael Gordon (Mar. 15, 2006) (Exhibit D). This list of desired deponents included several third parties and several residents of the United Kingdom.[5]

In response to Teva's request, GSK went to great lengths to ensure the prompt and voluntary appearance of all of the witnesses in advance of the May 31 fact discovery deadline. For example, rather than require Teva to utilize time-consuming and burdensome Hague Convention procedures, GSK voluntarily offered Dr. Owen (no longer employed by GSK) and other UK residents for deposition. With respect to the two named inventors:

- GSK offered Mr. Gallagher for deposition on April 21, *see* letter from Amy Wigmore to Karen Robinson (Mar. 29, 2006) (Exhibit E), *but Teva declined the offer due to other commitments and deferred the deposition to May 5.*
- Teva requested that the deposition of Dr. Owen occur on May 1, but Dr. Owen was not available on that date. On March 29, GSK informed Teva that Dr. Owen would be available on May 26. *See id.* Teva agreed to conduct the deposition on that date and at no time raised with GSK any complaint about the timing of this deposition.

**2. Depositions Requested by Teva in Late May 2006**

Teva also delayed in seeking testimony regarding the prosecution of the patents-in-suit by GSK's patent department. Teva had notice many months ago of the individuals within GSK's patent department involved in the prosecution of the patents-in-suit. GSK's October 3, 2005 interrogatory responses provided Teva with the names of persons involved in drafting the patent application for the '808 patent (William Edgerton) and the '860 patent (Vincent Fabiano and

[5] The following individuals were identified in Teva's March 15, 2006 letter: Brenda Costall (employee of Bradford University; UK resident); Roger Eden (former GSK employee; UK resident); Gregory Gallagher (former GSK employee; U.S. resident); Carol Harvey (current GSK employee; U.S. resident); Paul Hieble (current GSK employee; U.S. resident); William Huffman (current GSK employee; U.S. resident); David Owen (former GSK employee; UK resident).

Peter Giddings).[6] Nonetheless, Teva waited until the final days of the fact discovery period to seek depositions regarding patent prosecution.

- William Edgerton. Teva did not request the deposition of William Edgerton until *May 24*, one week before the close of fact discovery. After receiving this request, GSK attempted to contact Mr. Edgerton but learned that he had passed away in April.
- Peter Giddings. Teva first requested the deposition of Peter Giddings on *May 23*. Teva noticed this deposition for May 31. Mr. Giddings, who is a UK resident, was not available on that date, but GSK nonetheless agreed to make Mr. Giddings available for deposition in the United States after the May 31 fact discovery deadline.
- Rule 30(b)(6) Deposition of GSK regarding patent prosecution issues. Teva did not request a Rule 30(b)(6) deposition of GSK regarding patent prosecution issues until *May 19*.[7]

There is no reason Teva could not have noticed these depositions regarding patent prosecution issues months earlier, and Teva has offered no justification whatsoever for waiting until the close of discovery to do so.

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[6] *See* Plaintiff GSK's Responses to Defendant's First Set of Interrogatories, Responses to Interrogatory Nos. 2, 9 (Oct. 3, 2005) (Exhibit C). In its responses, GSK also noted that additional individuals may be identified from documents to be produced by GSK. Teva could have identified relevant individuals involved in patent prosecution even before GSK's October 2005 discovery responses, as names of relevant individuals are listed on the patents themselves as well as in the publicly available patent prosecution files.

[7] Teva served a Rule 30(b)(6) notice to GSK after the close of business on Friday, May 19, 2006. *See* Letter from Conley Manley to Michael Gordon, enclosing deposition notices (May 19, 2006) (Exhibit F). GSK subsequently informed Teva on May 30 that GSK was not aware of any current GSK employees other than Mr. Giddings (who was already noticed for deposition) with relevant personal knowledge of the prosecution of the '808 and '860 patents. Therefore, GSK suggested that a Rule 30(b)(6) deposition on patent prosecution issues would be unnecessary because it would not yield information in addition to that already made available to Teva through the production of the relevant files and deposition of Mr. Giddings. *See* Letter from Michael Gordon to Charanjit Brahma (May 30, 2006) (Exhibit G).

## V. Agreement Regarding Adjustments to Case Schedule

As the parties approached the May 31, 2006 fact discovery deadline, it became clear that certain discovery would need to occur after the May 31 cutoff. For example, because Teva did not request the deposition of Peter Giddings until May 23, 2006 this deposition could not be scheduled in May. Other delays by Teva resulted in two additional depositions (that were noticed weeks before the May 31 fact discovery deadline) being scheduled for June.[8] As a result, the parties agreed to extend the fact discovery deadline until June 30 *for the limited purpose* of responding to discovery requests and deposition notices served prior to May 31. [D.I. 70]

## VI. Teva's Untimely Assertion of New Claims

Despite numerous conferences with GSK and a June 5 teleconference with the Court regarding scheduling issues, Teva did not disclose its plans to assert new claims in this case until after the summary judgment deadline. Teva first informed GSK of its inequitable conduct allegations in its supplemental interrogatory responses served after the close of business on Friday, June 9, 2006.[9] The instant motion to amend was not filed until June 28, two weeks after the June 14 deadline for seeking permission to file summary judgment motions.

Most notably, despite the fact that Teva's planned expansion of the case would necessarily impact the case schedule, Teva was silent about its plans to add new claims during

[8] The deposition of Kevin Reeves, a GSK Rule 30(b)(6) witness, occurred in June after Teva, on May 25, informed GSK that it was unavailable to conduct the deposition on the agreed-upon date of May 31. *See* Letter from Charanjit Brahma to Amy Wigmore (May 25, 2006) (Exhibit H); Letter from Michael Gordon to Charanjit Brahma (May 26, 2006) (Exhibit I). In addition, Teva offered to make one of its own witnesses, Ann Payne (whose deposition was noticed on May 8), available for deposition in June. This deposition was originally scheduled for June 2, then rescheduled by agreement for June 14. *See* Letter from Michael Gordon to Charanjit Brahma (June 1, 2006) (Exhibit J).

[9] *See* Defendant Teva Pharmaceuticals U.S.A., Inc.'s Third Supplemental Responses to Plaintiff's First Set of Interrogatories (June 9, 2006) (Exhibit T).

the June 5 conference with the Court addressing scheduling issues. During the conference, Teva raised the possibility of moving the summary judgment deadline, but the Court made clear that no extension of the July 12 summary judgment hearing deadline would be granted. At no time did Teva inform the Court or GSK that such an extension might be warranted in light of new claims Teva planned to assert in the next few days.

## ARGUMENT

The grant or denial of a motion to amend is within the discretion of the Court. *Foman v. Davis*, 371 U.S. 178, 182 (1962). While leave to amend is often granted, "it is not automatic, and the liberal policy of granting leave to amend must not be interpreted to permit amendment without restraint." *Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 732 (D. Del. 2002). Rather, the Supreme Court has suggested several reasons that can justify denying leave including undue delay, bad faith or dilatory motive, prejudice, or futility of claims. *See Foman*, 371 U.S. at 182. Here, Teva's belated attempt to add significant new claims and defenses should be denied because Teva unduly delayed in bringing the claims and their assertion would prejudice GSK. To the extent that Teva's claims are not clearly futile on the face of the proposed amended complaint, GSK has been further prejudiced because it is too late for GSK to challenge Teva's claims on summary judgment.

### I. Teva's Motion Should Be Denied Because Of Teva's Undue Delay

#### A. Facts Relied Upon in Teva's Motion Were Not "Recently Discovered"

As set forth in detail above, Teva has long been on notice of the facts allegedly supporting many of its inequitable conduct arguments. For example, Teva argues that GSK committed inequitable conduct because Gallagher "never synthesized any compound covered by

the broad claims of the '808 patent other than ropinirole." Teva Br. at 6.[10] Likewise, Teva inaccurately claims that GSK committed inequitable conduct because the patent "suggests" that ropinirole hydrochloride was tested to determine an effective dose to achieve an anti-hypertensive effect in an average size human. *Id.* at 8. Teva claims its arguments on both of these points are the result of "recently discovered evidence" from Mr. Gallagher's deposition. *Id.* at 6-8.

Despite its claims to the contrary, Teva was on notice of these facts in October 2005, *nearly a month before the deadline to amend pleadings*, and nine months before its untimely motion to amend. In particular, GSK's October 3, 2005 response to interrogatories made clear that Mr. Gallagher's reduction to practice of the invention claimed in the '808 patent (a) involved only the synthesis of ropinirole, and (b) did not involve any human testing. If Teva believes (as it now claims) that it was inequitable conduct for GSK to obtain the '808 patent naming Gallagher as the sole inventor when Gallagher had synthesized only ropinirole and not other compounds, it should have raised that argument last October when it received GSK's description of the conception and reduction to practice. Likewise, if Teva believes (as it now claims) that it was inequitable conduct to procure the '808 patent without conducting human testing (because, as Teva inaccurately alleges, such testing was "suggested" by the patent), Teva should have made this claim last October, when it read GSK's description of the conception and reduction to practice, which made no mention of human testing. If Teva required additional information or clarification of these responses, it could have pursued the matter with additional discovery requests or by seeking depositions on these topics prior to the November deadline for amending

[10] All citations to Teva's brief refer to Defendant Teva Pharmaceuticals' Corrected Brief in Support of Motion for Leave to Amend its Answer, Defenses, and Counterclaims, filed on July 10, 2006.

pleadings. Instead, Teva neither asserted these claims nor sought additional discovery on them; rather Teva did nothing for more than five months, waiting until mid-March 2006 to seek any depositions.

Teva has likewise long been on notice of the facts related to its claims about the inventorship of the '860 patent. Teva suggests that scientists at Bradford University should have been named as co-inventors because of their work confirming Dr. Owen's belief that ropinirole could be used to treat Parkinson's Disease: "Dr. Owen admitted that he was not even the first to develop a definite and permanent idea that ropinirole or its hydrochloride salt could be used to treat Parkinson's Disease as claimed." Teva Br. at 10. Aside from the fact that no such admission occurred—and Teva notably does not cite any evidence in support of this claim[11]—Teva was on notice of Bradford University's role as of October 2005, a month before the November deadline to amend pleadings. In particular, in its interrogatory responses GSK described the conception and reduction to practice of the inventions claimed in the '860 patent, making clear that Bradford University conducted tests to confirm ropinirole's anti-Parkinson's effects.[12] Accordingly, Teva knew about Bradford's role in October 2005; if Teva believed (as it now claims) that Bradford's involvement creates an inequitable conduct claim, it should have pursued that claim last fall, or at the very least pursued additional discovery at that time on this issue.[13]

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REDACTED

[12] See Statement of Facts, Section IV.A. *supra*.

[13] Likewise, the sole document cited by Teva in support of this inventorship challenge—a September 1986 report to Dr. Owen from scientists at Bradford—was produced to Teva on December 16, 2005.

### B. Teva's Undue Delay in Seeking Depositions

As detailed above, Teva could have conducted discovery related to its allegations of inequitable conduct many months ago. Yet Teva waited until March 15 before making *any* requests for depositions in this case and until the *final days* of the discovery period to seek testimony regarding the prosecution of the patents-in-suit by GSK's patent department.

#### 1. Inventors

In an attempt to shift the blame to GSK for the late timing of the inventors' depositions, Teva incorrectly alleges that GSK purposely postponed these depositions until the end of the fact discovery period. *See, e.g.*, Teva Br. at 1. Teva's charges are preposterous in light of the actual course of discovery in this case. The fact that the inventors were deposed in May is due *entirely* to Teva's own delay and indeed request. As noted above, Teva waited until March 15, 2006 to request depositions of the inventors, both of whom are former employees of GSK residing outside the jurisdiction. After receipt of Teva's request, GSK promptly made the inventors available for deposition. Teva did not even request that Dr. Owen be deposed before May – it sought a May 1 deposition. Yet, illogically, Teva accuses GSK of "dilatory tactics" for not making Dr. Owen available until May. *See* Teva Br. at 15. With respect to Mr. Gallagher, Teva's charges are even more off the mark. GSK in fact offered Mr. Gallagher for deposition in *April* (specifically, April 21), but Teva chose to defer this deposition until May 5.[14] And then after taking Mr. Gallagher's deposition on May 5, Teva still waited almost two more months before bringing its motion to amend.

[14] Despite the fact that Teva chose to postpone the deposition of Mr. Gallagher, Teva claims, incorrectly, that Teva "took these depositions at the earliest dates offered by Plaintiffs, all of which came within the last month of the scheduled fact discovery." Teva Br. at 13.

### 2. Individuals Involved in Prosecuting the Patents-in-Suit

Teva's attempt to deflect blame for the delay in deposing individuals involved in patent prosecution is equally inappropriate. Teva did not even approach GSK about deposing *anyone* involved in the patent prosecutions until the closing days of fact discovery. Teva waited until May 19 to request a Rule 30(b)(6) deposition on patent prosecution issues;[15] until May 23 to seek the deposition of Mr. Giddings; and until May 24 to request the deposition of Mr. Edgerton (who had passed away the previous month). Had Teva diligently pursued its inequitable conduct theory it would have sought these depositions many months ago, and it could have done so any time after October 2005, when GSK's interrogatory responses informed Teva about which individuals were known to possess relevant knowledge about patent prosecution. *See* Plaintiff GSK's Responses to Defendant Teva's First Set of Interrogatories, Responses to Interrogatory Nos. 2, 9 (Exhibit C).

There is simply no justification for Teva waiting until the final days of fact discovery to request these depositions, and Teva has offered none. Teva, either strategically or carelessly, chose to wait until the very end of fact discovery to seek these depositions. In either case, Teva's own undue delay is responsible for its belated assertion of new claims, and thus Teva's motion to amend should be rejected as untimely. *See, e.g., Duggins v. Steak 'N Shake, Inc.*, 195 F.3d 828, 834 (6th Cir. 1999) (upholding denial of leave to amend where moving party "was obviously

[15] Likewise, Teva's claim that "only three weeks ago, Plaintiffs represented for the first time that they could not present a deposition witness with any personal knowledge about the preparation and prosecution of the '808 patent" (Teva Br. at 5), is remarkable given that Teva fails to acknowledge that Teva *did not ask for a witness on this topic until after the close of business on May 19. See* Letter from Corey Manley to Michael Gordon, enclosing deposition notices (May 19, 2006) (Exhibit F). None of the three attorneys listed on the face of the patent is still employed by GSK; Judge Lourie sits on the Federal Circuit and Mr. Edgerton is deceased. In any case, GSK had advised Teva in October 2005 of persons known to have knowledge regarding the prosecution of the patents-in-suit. *See* Statement of Facts, Section IV.B.2. *supra*.

aware of the basis of the claim for many months, . . . [yet] delayed pursuing this claim until after discovery had passed [and after] the dispositive motion deadline had passed. . . .").

## II. Teva's Motion Should Be Denied Because the Amendment is Prejudicial to GSK

### A. Teva's Proposed Amendment Would Prejudice GSK's Ability to Pursue Relevant Fact and Expert Discovery

A motion for leave to amend may also be denied where permitting the new claims would be prejudicial to the other parties. *See, e.g., Isaac v. Harvard University*, 769 F.2d 817, 829 (1st Cir. 1985) (upholding denial of motion to amend where new claims "very materially change the nature of the complaint"); *Ferguson v. Roberts*, 11 F.3d 696, 706 -707 (7th Cir. 1993) (amendment denied as prejudicial because it would add "new complex and serious charges" one month before the close of discovery); *Josey v. John R. Hollingsworth Corp.*, 996 F.2d 632, 642 (3d Cir. 1993) ("The district court found that amendment of Josey's pleadings after the close of discovery would prejudice the defendant. This court will not weaken the district court's control over its own docket by requiring a relaxation of pleading requirements."). Here, the late addition of Teva's inequitable conduct claims will prejudice GSK by limiting its ability to pursue relevant fact and expert discovery.

First, because these claims were not raised at all during fact discovery, GSK did not have the opportunity to conduct fact discovery in order to adduce evidence to rebut these arguments. For example, GSK has been deprived of the opportunity to obtain evidence from William Edgerton, who prosecuted the '808 patent but passed away in April. Had Teva asserted its inequitable conduct theories promptly, GSK would have had the opportunity to solicit testimony from Mr. Edgerton regarding the prosecution of the '808 patent, the specific arguments now asserted by Teva, and the custom and practice within GSK's patent department. *See, e.g., Boris v. Moore*, 253 F.2d 523, 524 (7th Cir. 1958) (denial of leave to amend upheld where relevant

witness "had died between the time the action was commenced and the date of the motion to amend" and defendant "had foregone the opportunity to question him about any [new claims] because supposedly no such relief was sought.").

Likewise, GSK would have had the opportunity before the close of fact discovery to obtain testimony from other third party witnesses who were involved in the prosecution of the patents-in-suit, aware of GSK's custom and practice in prosecuting patents in the mid 1980's, or otherwise could have knowledge relevant to Teva's allegations of inequitable conduct. Testimony on the practices of GSK's patent department in prosecuting patents would be particularly relevant because Teva's inequitable conduct claims relate to the manner in which generic claims are drafted.

Second, GSK is further prejudiced because the parties are currently in the middle of the expert discovery period, but Teva's new claims expand the scope of expert testimony. For example, Teva's new claims will likely require expert testimony relating to the generic claims of each of the patents-in-suit – claims that GSK is not asserting against Teva. In addition, the new claims may also require expert testimony on newly raised issues such as tachyphylaxis and human dose testing related to the '808 patent.[16] If these claims are permitted, GSK will be forced to prepare expert reports on very short notice. GSK must identify appropriate experts who are available immediately (i.e., not currently busy with other projects and not on vacation), as answering expert reports are due August 14. Moreover, the retention of these experts, and the work on their reports, will all need to occur at the same time that GSK is working on the expert reports on the issues that are already in the case. Furthermore, because GSK has not had the opportunity to adduce all the relevant facts to defend against Teva's inequitable conduct

[16] *See* Teva Br. at 7-8.

allegations, these experts may be in the untenable position of having to provide reports and testimony without the benefit of all of the facts related to these claims.

Third, because Teva seeks to add claims and defenses *after* the deadline for summary judgment motions, it has effectively deprived GSK of the right to seek summary dismissal of some or all of the new claims. GSK is prejudiced because it has been deprived the opportunity to eliminate (or at least narrow) Teva's claims on summary judgment.

### B. If Teva's Claims of Inequitable Conduct Had Been Timely Made, Each of Them Would Have Been Susceptible to Disposition by Summary Judgment

Teva's proposed amended pleading alleges six instances of inequitable conduct. Each of Teva's allegations flies in the face of the facts, the law, and in some instances common sense. Indeed, Teva's claims represent exactly the "plague" on the patent system that the Federal Circuit has condemned. *See Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague."). Here, it is a plague that implicates a sitting Federal Circuit judge who headed GSK's patent department at the time the patents-in-suit were prosecuted.

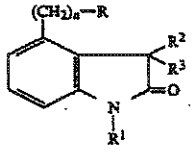
Most notably, Teva does not even attempt to cite evidence satisfying its high burden of demonstrating an intent to deceive, "a separate and essential component of inequitable conduct." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990). This absence of evidence would alone justify entry of summary judgment against Teva on the issue of inequitable conduct, *see, e.g.*, *Tenneco Automotive Operating Co. v. Visteon Corp.*, 375 F. Supp. 2d 366 (D. Del. 2005); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 873 (Fed. Cir. 1988)), but that is not the only flaw in Teva's claims. All of Teva's claims suffer from multiple other infirmities that would make them ripe for summary judgment had Teva asserted

them in the time required by the scheduling order in the case. Set forth below is a summary of the critical flaws in Teva's claims.

**1. The '808 Patent**

**a. Teva's Claim That Mr. Gallagher Filed A False Declaration Regarding Sole Inventorship is Meritless and Misconstrues the Requirements for Generic Patent Claims**

Like virtually all patents directed to chemical compounds, the '808 patent includes a claim to a generic formula (claim 1) that covers more than the chemical compound first discovered by the inventor. As depicted below, the generic formula of claim 1 identifies different elements ("substituents") that might be part of the compound at different positions on the molecule denominated by the notation "R," "$R^1$," "$R^2$," and "$R^3$."




A prior patent naming William Huffman as a co-inventor, (U.S. Patent No. 4,314,944, "the Huffman patent") disclosed a genus of compounds depicted in a similar drawing to that contained in the Gallagher patent, with one key distinction: the compounds claimed in the Huffman patent have a hydroxy (i.e,. oxygen and hydrogen) or methoxy group at the bottom of the ring on the left-hand side of the drawing, whereas the compounds described in the Gallagher patent do not. As set forth in the '808 patent, the invention of Mr. Gallagher was to discover that the compounds described in the Huffman patent, surprisingly, did not require the hydroxy group at that position in order to be active.

Dependent claim 5 of the '808 patent is directed to a specific compound falling within generic claim 1; namely, ropinirole hydrochloride. Because Teva has stipulated to infringement

of dependent claim 5 directed to ropinirole hydrochloride itself, claim 1 is no longer being asserted by GSK and its validity and enforceability are therefore not at issue unless Teva's motion to amend is allowed.

Teva apparently concedes that Mr. Gallagher is the proper inventor of claim 5, *i.e.* ropinirole hydrochloride. Nonetheless, Teva argues that Mr. Gallagher somehow committed inequitable conduct because of the failure to name an unidentified inventor involved in an undescribed way in the conception of generic claim 1. *See, e.g.*, Amended Complaint ¶ 43. The failure to identify who this supposed unnamed additional inventor is or what he or she allegedly did should be enough to dismiss any claim of improper inventorship. Even less plausible is a claim of inequitable conduct based on the failure to join an unnamed inventor for an unidentified contribution. Like any claim of inequitable conduct, one that is based on improper inventorship requires proof of deceptive intent. *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1318 (Fed. Cir. 2000) ("Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive"). There is a presumption that the inventors named on an issued patent are correct, so misjoinder of inventors must be proven by clear and convincing evidence. *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 979-980 (Fed. Cir. 1997). A motive on the part of Mr. Gallagher or someone else to deceive the patent office cannot be inferred or even imagined when the identity of the unnamed "inventor" is unknown.[17]

Teva's inequitable conduct claim is missing such a fundamental piece of evidence because it rests on a basic misunderstanding of what it takes to claim a generic formula and the

[17] This is particularly true where all the possible alleged co-inventors were employed by the same company, thereby eliminating any financial incentive for GSK to deceive the patent office about inventorship.

manner in which patent claims are drafted. In particular, there is no rule limiting patents to the precise product or method developed by an inventor. Patents routinely seek protection going beyond the specific work of the named inventor. If such protection could not be obtained, the value of patents would be severely compromised. The understood role of the patent attorney is to obtain claims as broad as possible under the patent statute consistent with what is described in the patent specification. Irving Kayton, Kayton on Patents at 3-1 (2d ed. 1983) ("During the prosecution stage the drafter will naturally attempt to write one claim that is as broad as the prior art of which he is aware will permit and that is supported by the disclosure in his patent application").

In seeking such claims, patent lawyers are guided by well-established principles concerning when an inventor is entitled to a generic claim. For example,

- The scope of enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. *In re Fisher*, 427 F.2d at 839.

- "Although one may envision a general concept, what one usually does first in making or isolating a chemical or chemical-related invention is to obtain a specific material or materials. One then broadens the concept to extend it as far as one envisions that other materials will have the same utility and can be similarly made. That broadened concept becomes the genus in a patent application that is both the broadest statement constituting a written description and usually claim 1." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 974 (Fed. Cir. 2002) (Lourie, J., concurring in decision to deny rehearing *en banc*).

- The number and variety of examples are irrelevant if the disclosure is "enabling" and sets forth the "best mode contemplated." *In re Borkowski*, 422 F.2d 904, 953 (C.C.P.A. 1970). A disclosure is enabling even if a considerable amount of experimentation is involved, if it is merely routine. *Ex parte Forman*, 230 USPQ 546 (B.P.A.I. 1986).

- "The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though

it is a factor to be considered along with all the other factors." MPEP § 2164.02 at 2100-195 (8th ed., rev. Oct. 2005).

- The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. *Atlas Powder Co. v. E.I. du Pont de Nemours and Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

- Every species need not be described in order that a generic claim meet the written description requirement. "A specification may, within the meaning of 35 U.S.C. §112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988).

In short, upon the discovery of ropinirole, Gallagher was entitled to a claim commensurate with the scope of his discovery, without regard to how many embodiments of the invention Gallagher had synthesized or whether or not some of the embodiments within a generic claim might be inoperative. An appropriately broad claim was drafted by a patent attorney at GSK and prosecuted with success in the patent office. This utterly ordinary process of obtaining patent protection does not lead to an inference that there was some unnamed inventor responsible for the generic claim, much less does it support a plausible claim of inequitable conduct. Instead, the facts surrounding the patenting of Mr. Gallagher's invention reflect the way patent protection is routinely obtained.

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The patent office allowed claim 1 with this fact clearly before it.

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If Claim 1 were asserted by GSK against Teva such that its validity could be challenged (which it is not), Teva might be able to assert a defense that it is overly broad under the enablement or written description requirements. It is, however, irresponsible of Teva to attempt to turn a garden variety defense under Section 112 into an inequitable conduct claim challenging the integrity of Mr. Gallagher and GSK's patent department. REDACTED

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**b. GSK's Statement Regarding the "Tachyphylaxis" Effects of Ropinirole Was Neither False Nor Material, and Teva Offers No Evidence of Intent to Mislead**

Teva's second inequitable conduct claim is based on the allegedly false nature of a statement in the '808 patent regarding "tachyphylaxis," a term defined by Teva as an increasing tolerance to a drug dose. Teva Br. at 7. Specifically, the '808 patent states that ropinirole hydrochloride did not cause tachyphylaxis in a particular experiment ("the perfused hind limb preparation") conducted by GSK. '808 Patent, col. 4, line 50 (Exhibit M). Teva's contention is meritless for at least three reasons.

First, the statement in the '808 patent is not false.

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Second, there is no basis for concluding that the statement in the patent concerning tachyphylaxis is material. Patentability of the compounds claimed in the '808 patent rested on

their unexpected cardiovascular activity. *See, e.g.*, '808 Patent, col. 1, lines 40-43 (Exhibit M). The existence or non-existence of tachyphylaxis was never a subject of prosecution, and is not even hinted at as a basis of patentability in the specification. The non-materiality of this issue is evidenced by the fact that it is not even mentioned in Teva's expert reports.

Third, there is no basis for inferring an intent to mislead the patent office.

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While Teva states that "Mr. Gallagher signed the inventorship declaration stating that he had reviewed and verified the statements in the patent application" (Teva Br. at 7), that is simply not true. The declaration is a verification only of Mr. Gallagher's belief that he is an inventor of the invention claimed. *See* Gregory Gallagher, Jr.'s Declaration and Power of Attorney (Dec. 6, 1982) (Exhibit N). The statement in the patent specification that no tachyphylaxis was observed in a particular experiment is indisputably true, and Teva has no evidence that Mr. Gallagher thought otherwise or knew of evidence to the contrary.

**c. Teva Mischaracterizes GSK's Immaterial Statements Regarding Effective Dose In Humans**

As is typical in pharmaceutical patents, the '808 patent includes information concerning possible doses. The entire discussion of dose in the '808 patent is as follows:

> Advantageously, doses selected from the dosage unit ranges given above will be administered several times, such as from one to five times, a day. The daily dosage regimen is selected from the range of about 50 mg to about 1.0 g, preferably 200-750 mg for oral administration and 50-500 mg for parenteral administration. When the method described above is carried out, $D_2$ -agonist activity is produced.
>
> For an average size human using 4-(2-di-n-propylaminoethyl)-2(3H)-indolone hydrochloride as an active ingredient, a typical

> dose to show anti-hypertensive activity would be selected from the range of from about 100-250 mg of base equivalent for each dosage unit which is adapted for oral administration and which is administered orally from 1-4 times daily.

'808 Patent, col. 5, line 59 - col. 6, line 5 (Exhibit M). According to Teva, this passage falsely "suggests" that actual human testing was performed to determine the disclosed range of doses. Teva Br. at 8.

Even if a "suggestion" could ever give rise to an inequitable conduct claim, there is no support for Teva's claim that the '808 patent would lead any person skilled in the art to believe that the quoted passage implied actual human testing. In the drafting of patents, the distinction between actual "working" examples and "prophetic" examples is well established. Working examples describe tests that have actually been conducted. MPEP § 608.01(p)(II) at 600-96. However, prophetic examples are also common in patents:

> Simulated or predicted test results and prophetical examples (paper examples) are permitted in patent applications. . . Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted.

*Id.* Working examples typically use the past tense to describe the actual work performed, while "[p]aper examples should not be described using the past tense. *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367, 66 USPQ2d 1385, 1394 (Fed. Cir. 2003)." MPEP § 608.01(p)(II) at 600-96; *see also Atlas Powder Co.*, 750 F.2d 1569 (affirming finding of no inequitable misconduct because prophetic examples were written in the present tense, thereby conforming with PTO requirements).

Here, the information describing dose is in the future and subjunctive tense: "Advantageously, doses selected from the dosage unit ranges given above ***will*** be administered several times," "[t]he daily dosage regimen *is* selected from the range of about 50 mg to about 1.0 g," "[f]or an average size human using 4-(2-di-n-propylaminoethyl)-2(3H)-indolone

hydrochloride as an active ingredient, a typical dose to show anti-hypertensive activity ***would*** be selected from the range of from about 100-250 mg." Thus, on its face, Teva's claim of inequitable conduct fails to meet the threshold requirement that a misrepresentation be made.

Furthermore, there is no support for an argument that the discussion of dose was material. Dose ranges were not a subject of prosecution of the '808 patent or a basis of patentability. There is accordingly no reason to think that a reasonable patent examiner would have cared whether the discussion of dose reflected a working or prophetic example. *See Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123 (Fed. Cir. 2006) (statement implying that actual clinical work was the basis of claimed surprising results was of low materiality even though the surprising results were the centerpiece of patent prosecution). The non-materiality of this issue is evidenced by the fact that it is not even mentioned in Teva's expert reports. And like all of Teva's claims of inequitable conduct, there is no evidence of intent to mislead the patent office by anyone involved in the patent prosecution.

**d. Teva's Arguments Regarding the Failure to Name Dr. Hieble as an Inventor are Illogical and Wholly Unsupported**

Presumably recognizing that it is missing a key element of an inequitable conduct claim, Teva attempts to compensate by arguing that Dr. Paul Hieble, a GSK scientist, should have been named as an inventor of the '808 patent and that he was not named as inventor for the express purpose of avoiding disclosure of an alleged piece of prior art. Importantly, Teva makes no attempt whatsoever to demonstrate why Dr. Hieble should have been named as an inventor. But even under Teva's inventorship theory, the burden would still rest on Teva to show at least that someone involved in the '808 prosecution knew that Dr. Hieble had knowledge of undisclosed prior art. Without such knowledge, Teva cannot, as a logical matter, prove its wholly unsupported allegation that "the applicant(s), their representatives and/or others substantively

involved in the prosecution of the applications that issued as the '808 patent intentionally omitted Mr. Hieble from the list of inventors for the '808 patent." Teva Br. at 9. Furthermore, "[w]hen an alleged omitted co-inventor does not claim to be such, it can hardly be inequitable conduct not to identify that person to the PTO as an inventor." *Pro-Mold and Tool Company, Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1576 (Fed. Cir. 1996). Thus, Teva has not and cannot plead a critical element of this inequitable conduct claim.

**2. The '860 Patent**

**a. Teva's Inventorship Allegations are Baseless and Contradicted by the Evidence Adduced Through Discovery**

With respect to the '860 patent, Teva recycles the same inventorship claim it makes regarding the '808 patent to argue that Dr. Owen, the named inventor, committed inequitable conduct merely by claiming a genus broader than ropinirole. Teva adds to this misguided inventorship argument a second argument suggesting that Professors Brenda Costall and R.J. Naylor of the University of Bradford should have been named inventors based on the non-sequitur that they authored the first document describing the use of ropinirole as an anti-Parkinson's agent after conducting tests commissioned by Dr. Owen.

As with the '808 patent, there is no basis for Teva's suggestion that an inventor of a chemical compound or a method of using such a compound cannot claim a genus covering the compound to the fullest extent supported by the patent specification. The basis of patentability of the '860 patent was that the indolone derivatives described in the '808 patent surprisingly showed an anti-Parkinson's effect. *See* '860 Patent, col. 1, lines 48-58 (Exhibit O). This was supported with a description of test results using ropinirole.

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Naturally enough in

light of the nature of the invention and the prior art (which included the '808 patent), the application for the '860 patent presented claims that generally correspond to the compounds described in the '808 patent for use as an anti-Parkinson's treatment. Notwithstanding the lack of an express disclosure of test results using specific compounds other than ropinirole, the patent office agreed that Dr. Owen was entitled to claim 1 and issued the patent.

Whether the patent office's decision was correct is not at issue, as GSK only asserts claim 3 (directed to a method of treatment of Parkinson's Disease using ropinirole hydrochloride). There is no justification for making the invalidity of claim 1 an issue indirectly through Teva's claim of inequitable conduct.

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The claim that the researchers at Bradford University should be named as inventors is equally meritless.

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**b. Teva Mischaracterizes GSK's Statements Regarding Bromocriptine and its Inequitable Conduct Allegations Lack Evidence of Materiality or Intent**

Teva identifies an alleged mistake in the '860 patent, and then moves to make it into an inequitable conduct claim notwithstanding the absence of any evidence of materiality or intent. In the background section of the patent, prior art compounds to treat Parkinson's Disease called "ergot alkaloids" are described and criticized for their side effects. '860 Patent, col. 1, lines 36-44 (Exhibit O). One of these compounds is bromocriptine, which is described as a "post-synaptic" dopamine agonist.

The description of bromocriptine as "post-synaptic" appears to have been correct.[18] But even if the statement was erroneous, there is no indication that the error was either intentional or

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material to patentability. The compounds of the '860 patent are indolones having a fundamentally different structure than ergot alkaloids. The basis of patentability was that these indolones had a central nervous system effect contrary to what was previously thought. *Id.*, col. 1, lines 48-58. The description of the ergot alkaloids and their side effects in the patent is solely as a predicate for the conclusion that there was a continuing need for effective treatments of Parkinson's. *Id.*, col. 1, lines 35-48.

Nothing in the patent or its prosecution supports the proposition that whether bromocriptine was or was not "post-synaptic" would have been material to the prosecution of the '860 patent.

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REDACTED Teva's corrected filing of July 10, 2006 acknowledges this fact, one that is fatal to its already strained argument that the discussion of bromocriptine in the '860 patent somehow forms the basis for an inequitable conduct claim. Inexplicably, Teva continues to cite this episode in support of its meritless claim rather than abandon the claim outright.[20] There is no ready procedure to correct mistakes in United States patents after they have been issued, much less an obligation to do so. Accordingly, Teva has no basis for insinuating deceptive intent based on the fact that "the false statement regarding the post-synaptic activity of bromocriptine was brought to the attention of GSK patent attorneys or agents involved in the prosecution of the '860 application after it issued." Teva Br. at 12. Instead, GSK's prompt correction of the alleged error when it was brought to its attention in Europe belies any suggestion that it purposely made an erroneous statement in the application when it was filed.

## CONCLUSION

For the reasons set forth above, GSK respectfully requests that the Court deny Teva's motion to amend. In particular, Teva has long been on notice of the facts cited in its papers; and to the extent that Teva needed additional deposition testimony on these issues, Teva simply failed to seek that testimony until the end of discovery. Furthermore, Teva's amendment would

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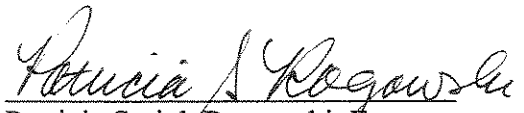
[19] In addition, Teva's revised filing corrects a blatant misstatement that Dr. Owen was a co-author of a 1986 publication that Teva alleges GSK improperly failed to disclose to the patent office.

[20] Teva's strained attempt to resuscitate this misguided accusation results in the following illogical allegation from its proposed amendment: "Furthermore, although the false statements in the '860 patent were brought to the attention of Plaintiffs' patent attorneys and/or agents involved in the prosecution of the '860 patent application *after it issued*, neither Plaintiffs nor Dr. Owen took steps to correct the false statements in the '860 patent specification." *See* Corrected First Amended Answer, Defenses, and Counterclaims of Defendant Teva Pharamaceuticals USA, Inc. at ¶ 62 (emphasis added).

significantly prejudice GSK by denying it the opportunity to conduct fact discovery made relevant by Teva's new claims and by disrupting and expanding the scope of expert discovery. Finally, Teva's belated assertion of its new claims would deprive GSK the opportunity to seek their dismissal by summary judgment. Accordingly, Teva's motion should be denied.

Alternatively, should the Court determine to allow the motion to amend, the current case schedule cannot be maintained. A conference should therefore be held to establish a new schedule for expert discovery, summary judgment, and trial.

SMITH KLINE & FRENCH LABORATORIES LIMITED AND SMITHKLINE BECHAM CORPORATION, D/B/A GLAXOSMITHKLINE
Respectfully submitted,



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Dated: July 13, 2006

**Redacted Version of**
**DI 77 Filed 7/21/06**

## CERTIFICATE OF SERVICE

I, Patricia Smink Rogowski, hereby certify that on July 13, 2006 **PLAINTIFF GLAXOSMITHKLINE'S BRIEF IN OPPOSITION TO DEFENDANT'S MOTION FOR LEAVE TO AMEND ITS ANSWER, DEFENSES, AND COUNTERCLAIMS** using CM/ECF which will send notification of such filing to the following:

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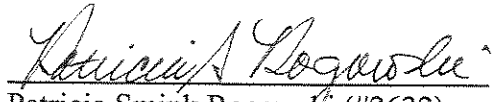
**DI 77 Filed 7/21/06**



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